

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
_____)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (FDS)
THIS DOCUMENT RELATES TO:)	
)	
All Actions)	
_____)	

**SAINT THOMAS ENTITIES’ MEMORANUDM OF LAW IN SUPPORT OF
PROPOSAL FOR PLAINTIFF’S FACT SHEET AND RECORDS AUTHORIZATIONS**

Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the “Saint Thomas Entities”) file this Memorandum of Law in Support of their Proposal for a standardized Plaintiff’s Fact Sheet and Records Authorizations in accordance with the Court’s order of January 7, 2014 (Docket #748), and in support show as follows:

INTRODUCTION

Fact sheets and standardized authorizations for the release of records held by third parties are being used in personal injury multi-district litigations in lieu of formal interrogatories and requests for production. They are typically more “user-friendly” for the individual plaintiffs—designed to be like the medical questionnaires that doctors often require their patients to complete. There are two major purposes for fact sheets and authorizations—(i) to seek information necessary to identify potential bellwether cases for test trials; and (ii) to insure that records are preserved for all Plaintiffs, whether selected for initial trials or not.

The Saint Thomas Entities’ proposal for a Plaintiff’s Fact Sheet (“STE PFS”) (Exhibit A) and authorization forms (Exhibits B-F) accomplish both purposes. The PFS is designed to discover individual medical and related information for each Plaintiff who has made claims

against these defendants. The form and questions are loosely patterned on fact sheets that have been agreed to by parties and/or approved by courts in other MDLs, although they have been tailored to elicit critical information necessary to evaluate the individual claims in this litigation. The records authorizations are simple, standard, and place no burden on the Plaintiffs to gather third-party documents.

There is no real dispute that the information and records sought by the STE PFS and authorizations are relevant and discoverable in connection with Plaintiffs' personal injury/wrongful death claims. The only issue is *when* that discovery should occur. The PSC's position is that only minimal information is necessary to choose bellwether plaintiffs. In fact, their initial proposal was that the bellwether pool be chosen by a date certain without providing any process for making the necessary determinations. After meeting resistance from the Saint Thomas Entities and other defendants, the PSC proposed a "profile form" process through which the "Confidential Personal Injury or Wrongful Death Claim Information Form" developed by the bankruptcy court (for ascertaining the value of claims in that proceeding) would be used to identify the initial bellwether pool of personal injury trials. Only those particular chosen individuals would be subject to full-blown discovery. The PSC further proposed that all medical records produced by third parties be vetted through its proprietary records repository, affording the PSC lawyers the opportunity to screen them and unilaterally determine which ones were "relevant" and so would be produced to the Defendants for bellwether decisions. Judge Saylor rejected that proposal and referred the matter to this Court for resolving the form of an appropriate fact sheet and records authorizations.

In accordance with Judge Saylor's direction and this Court's January 7 order, the parties have spent considerable time meeting and conferring and exchanging drafts of proposed fact

sheets/profile forms,¹ and both sides have made concessions in an effort to try and reach a compromise. But there are still a number of issues where their positions are far apart, necessitating this Court's intervention. As explained, the Saint Thomas Entities propose that the Court adopt their proposed PFS for the reasons set forth below.

ARGUMENT AND AUTHORITIES

I. The Bellwether Process Should Be Informed by the Fact Sheets and Medical Records

In appropriate circumstances, bellwether trials (also referred to as test cases) can be used to glean important information about the claims of the litigation as a whole. *See* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (“[T]o produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases.”). Bellwether procedures have been used in an increasing number of mass tort MDLs. *See* Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2324-25 (June 2008) (Exhibit F).² As the Fifth Circuit has aptly summarized:

A bellwether trial designed to achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants has as a core element representativeness -- that is, the sample must be a randomly selected one of sufficient size so as to achieve statistical significance to the desired level of confidence in the result obtained.

¹ The Saint Thomas Entities have no issue with the title of the form—whether it is a “Fact Sheet” or “Profile Form,” as long as it contains adequate requests to obtain “the important, basic information” necessary to make informed decisions regarding the bellwether process. Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *The Problem of Multidistrict Litigation: Bellwether Trials in Multidistrict Litigation*, 82 TUL. L. REV. 2323, 2352 (June 2008) (Exhibit G) [hereinafter *Bellwether Trials*].

² The term bellwether “is derived from the ancient practice of belling a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context.” *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997).

Such samples are selected by the application of the science of inferential statistics. The essence of the science of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole.

In re Chevron U.S.A., Inc., 109 F.3d 1016, 1019-20 (5th Cir. 1997). As a result, “[i]t is critical to as successful bellwether plan that an honest representative sampling of cases be achieved.” *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2010 WL 4024778, at *1 (S.D. Ill. Oct. 13, 2013); *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (“[T]est cases should produce a sufficient number of representative verdicts and settlements to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis, and what range of values the cases may have if resolution is attempted on a group basis. The more representative the test cases, the more reliable the information about similar cases will be.”). As Judge Fallon indicated, “[i]f bellwether trials are to serve their twin goals as informative indicators of future trends and catalysts for an ultimate resolution, the transferee court and the attorneys must carefully construct the trial-selection process. . . . Any trial-selection process that strays from this path will likely resolve only a few independent cases and have a limited global impact.” Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2343.

Based on his extensive experience in the Vioxx and Propulsid MDLs, Judge Fallon has set out important principles for selecting bellwether trials. He suggests that although there is no “one-size-fits-all” procedure, there are certain sequential steps that should be followed in crafting the protocols and processes. First, the MDL court must be in a position to catalogue the “Entire Universe of Cases,” meaning that it “conduct[s] a census of the entire litigation and identif[ies] all the major variables.” *Id.* at 2344. The next step is for the court and the attorneys for both sides to “creat[e] a pool of cases that accurately represents the different divisions within the MDL from which the bellwether cases will be selected.” *Id.* at 2346. To fill the pool, there are

different methods—random selection, selection by the MDL court, and selection by the attorneys. *Id.* at 2348-49. And there are many variables within each strategy for filling the pool, all of which need to be geared to finding a truly representative, and therefore, credible sampling. *Id.* at 2348-60. After the trial-selection pool has been determined, the parties conduct case-specific discovery. *Id.* at 2360. Then the third step is to select individual cases from the pool, which also can be done in a variety of ways depending on the facts and circumstances. *Id.* at 2360-65.

At this point, it is not even clear if bellwether trials would be appropriate in this litigation. *See, e.g., Auchard v. Tenn. Valley Auth.*, No. 3:09-CV-54, 2011 U.S. Dist. LEXIS 14771, at *11-14 (E.D. Tenn. Feb. 2, 2011) (finding, after initial discovery, that bellwether cases were not appropriate because, based on the known information, the cases were not numerous enough (having 450 plaintiffs) and there was insufficient commonality between the cases). No bellwether selection procedure has been established, and in fact, virtually no discovery has occurred as to any Plaintiff. *See cf. In re: Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, No. 1:00-1898, MDL 1358 (SAS), M21-88, 2007 WL 1791258, at *3 (S.D.N.Y. June 15, 2007) (approving plan developed after investigation and discovery revealed particular variables in litigation census).

The first step in the process is to gather the facts relative to the individuals who could be potential bellwethers. *See Abrams v. Ciba Specialty Chems. Corp.*, No. 08-00068-WS-B, 2008 U.S. Dist. LEXIS 86487, at *16-19 (S.D. Ala. Oct. 23, 2008) (demonstrating the importance of having data and discovery to determine bellwether plaintiffs). As Judge Fallon explained:

An important factor in how the discovery process proceeds is the shape the case is in when it is filed and when discovery begins. Bellwether trial-candidate cases are no different from the typical non-MDL case—the less information that is known when a case is selected to fill the pool, the longer the discovery process will be. Therefore, to ensure that the case-specific discovery process progresses

in an expeditious manner, it is vital that only cases that are close to being trial-ready be considered to fill the trial-selection pool.

Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2351-52. “[T]rial-ready means the attorneys have adequate proof of the important, basic information . . . [including] the plaintiffs’ medical files and sufficient evidence tending to prove who had prescribed the drug, that the litigants had taken the drug, and what damages were allegedly suffered.” *Id.* at 2352. It is precisely this information that the Saint Thomas Entities seek through their PFS and authorizations.

II. The STE Proposed PFS and Authorizations Elicit “Adequate Proof of the Important, Basic Information”³

As noted above, the proposed STE PFS (Exhibit A) is patterned on fact sheets that have been used in other MDLs and mass tort proceedings. Although it has clearly been tailored to the facts of this case as they are currently known, many of the questions are standard for any claim involving bodily injury. *See, e.g.*, Fact/Profile Sheet Forms from Vioxx, Denture Cream Products, Paxil MDLs, and Alabama CT Scan litigation (Exhibits H-K). Considering the wide range of personal injuries claimed to have been associated with the NECC steroids,⁴ it is necessary to ask a wide range of questions about the Plaintiffs’ general health history, which bears on a variety of issues in the anticipated trials, such as co-morbidities, potential confounding circumstances, life expectancies, and the overall damages. The last thing the Court or any of these parties should want is a full trial of a case that turns out to be an outlier—expending considerable resources, yet revealing no useful information. *See, In re Yasmin*, 2010 WL 4024778, at *2 (Under such circumstances, “[l]ittle credibility will be attached to this process,

³ Fallon, *Bellwether Trials*, 82 TUL. L. REV. at 2352.

⁴ *See, e.g.*, Kainer M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone in Tennessee*, 367 NEW ENG. J. MED. 2194, 2194, 2198 (Dec. 2012) (Exhibit L).

and it will be a waste of everyone's time and resources" that ultimately derails resolution of the MDL).

In a spirit of compromise, the Saint Thomas Entities have agreed to defer a number of important matters to the second phase of the process, after the bellwether initial pool is chosen. Those compromises are evidenced on Exhibit M, which shows those changes as redlined draft against their initial PFS proposal. Through that process, the parties have identified some fundamental, philosophical differences that are implicated in multiple questions, including:

- Whether Plaintiffs' relevant medical history period should be ten years or limited to five years;
- Whether Plaintiffs should be required to answer questions about their tobacco, alcohol, and illicit drug use;
- Whether Plaintiffs can limit discovery of their pharmaceutical records to the time "since your exposure to the recalled product(s);"
- Whether Plaintiffs claiming emotional distress and related damages can limit their psychological and psychiatric histories to a three-year period from January 1, 2009 until January 1, 2012;
- Whether Plaintiffs should have to disclose any medical information, including relating to congenital conditions, about their relatives;
- To what extent Plaintiffs should have to disclose their calculations of lost earnings and earning capacity; and
- Whether discovery as to applications by individual Plaintiffs for Social Security or other disability benefits should be limited to awards actually received.

Because the parties continue to negotiate, this list may further change before the hearing, and the Saint Thomas Entities reserve the right to brief the issues in response to the PSC's simultaneous submission once it is received. For present purposes, it is important to note that numerous courts have approved fact sheets or profile forms that require mass-tort plaintiffs to provide the same types of information in the STE PFS at this initial stage. Further, Plaintiffs' attempt to defer this

“important, basic information” for the vast majority of their clients threatens to compromise both the bellwether selection process and Defendants’ ability to obtain sufficient medical records on all of the MDL Plaintiffs in the event they ultimately go to trial.

CONCLUSION AND PRAYER

For these reasons, Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health respectfully request that the Court: (i) approve and adopt their proposed Plaintiff’s Fact Sheet (Exhibit A) and order that each Plaintiff in the MDL with claims against the Saint Thomas Entities complete the approved form within 60 days of the date of its order; (ii) approve and adopt their proposed records authorizations (Exhibits B-E) and order execution of such authorizations by all Plaintiffs with claims against these Defendants within 60 days of the date of the order; and (iii) grant such other and further relief to which the Saint Thomas Entities are entitled.

Respectfully submitted,

SAINT THOMAS WEST HOSPITAL,
FORMERLY KNOWN AS ST. THOMAS
HOSPITAL, SAINT THOMAS NETWORK,
AND SAINT THOMAS HEALTH

By its attorneys,

/s/ Sarah P. Kelly

Sarah P. Kelly (BBO #664267)

skelly@nutter.com

NUTTER McCLENNEN & FISH LLP

Seaport West

155 Seaport Boulevard

Boston, Massachusetts 02210

(617) 439-2000

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OF COUNSEL:

Yvonne K. Puig*
Texas State Bar No. 16385400
Eric J. Hoffman*
Texas State Bar No. 24074427

FULBRIGHT & JAWORSKI L.L.P.
98 San Jacinto Blvd. Suite 1100
Austin, Texas 78701
(512) 536-2450
(512) 536-4598 (FAX)

*Appearing *Pro Hac Vice*

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 24th day of January, 2014.

/s/ Sarah P. Kelly

SARAH P. KELLY